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DARBY & DARBY P.C.
P.O. BOX 770
Church Street Station
New York, NY 10008-0770

EXAMINER

WRIGHT, PATRICIA KATHRYN

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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10/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/748,389	Applicant(s) YAMAKAWA ET AL.	
	Examiner P. Kathryn Wright	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-22 and 24-50 is/are pending in the application.
- 4a) Of the above claim(s) 3-7,24-28 and 41-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 8-22, 29-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's Response, filed August 15, 2007, to the outstanding Office action is hereby acknowledged and has been considered. Claims 2, and 22 have been cancelled. Any objection/ rejection not repeated herein has been withdrawn.

Election/Restrictions

2. Applicant's election of Group I, species i(a), in the reply filed on August 15, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

Art Unit: 1797

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 8-10, 12, 15, 19-22, 29-31, 33 and 39-40 are rejected under 35

U.S.C. 102(b) as being anticipated by US Patent no. 6,277,258 to Ivory et al.

(hereinafter "Ivory").

Ivory teaches a microfluidic device comprising a source fluid flow channel (sample channel) "capable of" receiving one or more sample molecules and a target fluid flow channel (electrolyte channel). The target fluid flow channel being in fluid communication with the source fluid flow channel at a cross-channel area, wherein a porous membrane (conductive membrane 16) separates the source fluid flow channel from the target fluid flow channel in the cross-channel area. Note that the source fluid flow channel and target fluid flow channel are formed in substrate, see Figs. 3A-6B (claim 15). Ivory also teaches a field-force/gradient mechanism (electrode array 98) proximate the porous membrane which generates an electric field. The magnitude of the field gradient may be manipulated by adjusting the voltage applied to the electrodes.

The porous membrane of Ivory is capable of passing at least one sample molecule (i.e., small ionic species) therethrough (see par. [0112]), thereby acting as a sensor in the same manner as that disclosed in the instant application. Ivory also teaches a light source and detector focused at the cross-sectional area (see col. 14, lines 6 et seq).

With respect to the porous membrane being "capable of" passing at least one

Art Unit: 1797

sample molecule from the source fluid flow to the target fluid flow and the source fluid flow channel being "capable of" receiving one or more sample molecules, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Even if positively recited in the claim, the Examiner asserts that the source fluid flow channel does receives one or more sample molecules from inlet source and the porous membrane of Ivory allows ions (i.e., small charged molecules) to pass through (see example at col. 19, lines 54 et seq). Giving the claims the broadest reasonable interpretation, these ions could be the "sample molecules" being isolated. Furthermore, nothing in the claim differentiates the "sample molecule" from the "ionic species" of Ivory.

Please note that a recitation with respect to the manner in which a claimed apparatus is intended to be employed, (i.e., disposed or reused) fails to differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

6. Claims 1, 8-10, 12, 15, 19-22, 29-31, 33 and 39-40 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Pub. no. 2006/0124459 to Strand et al. (hereinafter "Strand").

Strand teaches a microfluidic device (see par. [0113]) comprising a source fluid

flow channel (Fig. 2; sample channel) and a target fluid flow channel (Fig. 2; electrolyte channel). The target fluid flow channel being in fluid communication with the source fluid flow channel at a cross-channel area, wherein a porous membrane (Fig. 2; conductive membrane) separates the source fluid flow channel from the target fluid flow channel in the cross-channel area. Note that the source fluid flow channel and target fluid flow channel are formed in substrate, see Figs. 7A-C (claim 15). Strand also teaches a field-force/gradient mechanism (electrode array 98) proximate the porous membrane which generates an electric field. The magnitude of the field gradient may be manipulated by adjusting the voltage applied to the electrodes.

The porous membrane is capable of passing at least one sample molecule (i.e., small ionic species) (see par. [0112]), thereby acting as a sensor in the same manner as that disclosed in the instant application. Strand also teaches a light source and detector (UV-Vis spectrometer) focused at the cross-sectional area (see par. [0121]-[0122] and par. [0141]).

As discussed above with respect to Ivory, the porous membrane of Strand is "capable of" passing at least one sample molecule from the source fluid flow to the target fluid flow, and the source fluid flow channel being "capable of" receiving one or more sample molecule. It has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Even if positively recited in the claim, the Examiner asserts that the source fluid flow channel does receives one or more sample molecules from inlet source and

Art Unit: 1797

the porous membrane of Strand allows ions (i.e., small charged molecules) to pass through (see example at col. 19, lines 54 et seq). Giving the claims the broadest reasonable interpretation, these ions could be the "sample molecules" being isolated. Furthermore, nothing in the claim differentiates the "sample molecule" from the "ionic species" of Strand.

Please note that a recitation with respect to the manner in which a claimed apparatus is intended to be employed, (i.e., disposed or reused) fails to differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 11, 13-18, 32, 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent no. 6,277,258 to Ivory or US Patent Pub. no. 2006/0124459 to Strand, in view of US Patent No. 6,248,539 Ghardiri et al., hereinafter ("Ghardiri").

The teachings of Ivory and Strand have been summarized *supra*.

Ivory and Strand do not teach a microfluidic device having a single crystal or polysilicon porous membrane integrally formed on a silicon substrate. Furthermore, Ivory does not explicitly set forth the thickness of the membrane.

Ghardiri teaches a microfluidic device having a porous layer or membrane integrally formed on a single crystalline, or amorphous silicon substrate. The use of the porous silicon membrane makes possible the highly sensitive detection, identification and quantification of small analyte molecules at low concentrations (see col. 3, lines 59-63 and col. 5, lines 21+). The thickness of the membrane is between the range of 0.5 to 30 microns see col. 3, lines 30+ (claims 11, 32). The system of Ghardiri also includes a light source and CCD detector in communication with data collection equipment that collects data pertaining to changes in the optical characteristic of the porous membrane.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to use the porous silicon substrate of Ghardiri in the microfluidic system of Ivory or Strand since the use of the porous silicon substrate makes possible highly sensitive detection, identification and quantification of small analyte molecules (see abstract).

With respect to claims 14, 16 and 37, neither Ivory, Strand nor Ghardiri explicitly states the use of a porous membrane made of porous polysilicon and a substrate made of polydimethyl siloxane (PDMS).

However, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to use a porous polysilicon membrane and porous silicon substrate in the combined microfluidic system of Ivory and Ghardiri or Strand and Ghardiri, since the use of these types of porous membranes are well known and suited for molecular separation. Similarly, the use of polydimethyl siloxane is desirable since it is chemically inert and inexpensive.

Furthermore, with respect to the materials of construction, it would have been obvious to one of ordinary skill in the art to determine the optimum materials of construction based on considerations such as cost, ease of manufacture, reactions with the processing agents and/or maintaining the required reaction conditions.

Response to Arguments

10. Applicant's arguments, filed August 15, 2007, have been fully considered but they are not persuasive. With respect to the previous rejection of claims 1-2, 8-10, 12, 15, 19-23, 29-31, 33 and 39-40 under 35 U.S.C. 102(e) as being anticipated by US Patent Pub. no. 2006/0124459 to Strand, Applicant argues that Strand does not teach or disclose a porous membrane through which a sample molecule may pass. Specifically, the pore size of the Strand membrane is such that all molecules designated as samples will be retained in the sample chamber. Applicant alleges this is in contrast

to the instant claims which are directed to microfluidic device with a porous membrane that allows at least one sample molecule to pass through the membrane from the source fluid flow channel to the target fluid flow channel.

The Examiner respectfully disagrees with Applicant's argument. First, the porous membrane is claimed as being "capable of" passing at least one sample molecule from the source fluid flow to the target fluid flow. It has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. It is incumbent upon Applicant to show that the application disclosed by the prior art is not actually capable of performing such functions.

Secondly, the Examiner assert that even if the porous membrane is positively recited in the claim the porous membrane of Strand does allow ions (i.e., small charged molecules) to pass through (see paragraph [0112]). Giving the claims the broadest reasonable interpretation, these ions (charged molecules) could be the desired "sample molecules" separated from the source fluid flow channel. Furthermore, nothing in the claim differentiates the "sample molecule" from the "ionic species" of Strand.

Applicant argues that Strand's electrolyte channel is not equivalent to the target fluid flow channel as no sample molecules are allowed to pass into the electrolyte channel. Also, Strand's electrolyte channel is allegedly not a flow channel as presently claimed. Applicant alleges that the Strand electrolyte channel contains a static well of electrolyte fluid without any flow.

Again, the Examiner respectfully disagrees with Applicant's assertions. First, the ionic species (i.e., sample molecules) do pass through the porous membrane into the electrolyte channel, see paragraph [0112]. Secondly, the Examiner cannot find the "static well" of the electrolyte channel. Strand recites throughout the disclosure fluid flow through the second, or electrode chamber (see for example, paragraph [0079]). See also claim 18 of Strand, which recites an electrode chamber comprising an electrode array and an inlet for introducing a second liquid into the electrode chamber and an outlet for exiting the second liquid from the electrode chamber. Clearly, the electrolyte chamber is a channel through which the second fluid flows from the inlet to the outlet.

Therefore, for the reasons delineated above, the rejection of claims 1-2, 8-10, 12, 15, 19-23, 29-31, 33 and 39-40 under 35 U.S.C. 102(e) as being anticipated by US Patent Pub. no. 2006/0124459 to Strand is maintained.

Conclusion

11. No claims allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within


Art Unit: 1797

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jill Warden
Supervisory Patent Examiner
Technology Center 1700